IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA *ex rel.* PETER HUESEMAN,	)	
Plaintiff,	)	**SA-14-CA-212-XR**
v.	)	**FILED UNDER SEAL**
PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, INC.,	)	
Defendant.	)	

THE UNITED STATES OF AMERICA'S
COMPLAINT IN PARTIAL INTERVENTION

The United States of America (the "United States" or the "Government"), on behalf of the United States Department of Defense ("DOD"), brings this civil action against Defendant Professional Compounding Centers of America, Inc. ("PCCA") to recover treble damages and civil penalties under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and to recover damages under the federal common law theories of payment by mistake, unjust enrichment, and common law fraud, for losses sustained by TRICARE, the federal health care program for active duty military personnel, military retirees, and military dependents.

I. NATURE OF ACTION

1. PCCA is a supplier of active pharmaceutical ingredients and bases (collectively referred to herein as "ingredients") used in compound drugs. From at least March 2012 through May 2015, PCCA established and reported fraudulently inflated Average Wholesale Prices ("AWPs") for many of its ingredients relative to the actual prices at which it sold those ingredients (hereinafter "selling price") to its compound pharmacy customers (hereinafter

"customers"). TRICARE uses the AWPs for each ingredient in a compound drug to determine the amount pharmacies are reimbursed for the compound prescription claims they submit. PCCA used its inflated AWPs (and increased reimbursement levels) to induce its compound pharmacy customers to purchase its ingredients, knowing those customers would seek reimbursement from TRICARE for compound prescription claims at inflated amounts based on PCCA's AWPs. As a result of PCCA's actions, TRICARE paid hundreds of millions of dollars in excess reimbursement for false and fraudulent compound prescription claims submitted by PCCA's customers.

2. PCCA purchases active pharmaceutical ingredients from chemical and ingredient manufacturers, repackages those ingredients, and resells them to compound pharmacies for use in compound medications. PCCA also sells bases, such as creams and gels, into which those active pharmaceutical ingredients are added during the compounding process.[1] Generally, for each active pharmaceutical ingredient and base that PCCA sells, PCCA reports an AWP to commercial publishers of drug pricing data.

3. PCCA knew that TRICARE was a federal health care program.

4. PCCA's scheme to establish and report fraudulently inflated AWPs caused false and fraudulent claims to TRICARE resulting in excessive reimbursement amounts to PCCA's pharmacy customers for compound prescription claims containing PCCA's ingredients.

[1] "Compounding is generally a practice in which a licensed pharmacist . . . combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." *See* https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding (last visited October 28, 2021).

5. PCCA knew that its customers submitted compound prescription claims to third-party insurance payers, including TRICARE, for PCCA ingredients. PCCA knew that the AWPs it reported for its ingredients impacted the reimbursement amounts its pharmacy customers received for such claims.

6. To illustrate, in 2014, PCCA frequently sold the ingredient fluticasone propionate (NDC No. 51927-4330-00)[2] to certain compound pharmacy customers for between approximately $135 and $197 per gram but reported an AWP for the ingredient of $3,630.90 per gram. Similarly, in 2014, PCCA frequently sold the ingredient resveratrol (NDC No. 51927-4367-00) to certain customers for under $2 per gram but reported an AWP of $818.68 per gram.

7. The difference between an ingredient's AWP and its actual selling price represented the "spread," or the potential profit a pharmacy could make by purchasing, using, and billing for PCCA's ingredients. PCCA knew that many of its compound pharmacy customers placed a high value on ingredients with high AWPs or large "spreads." Because PCCA established both the AWPs it reported for its ingredients and the actual selling prices of its ingredients, PCCA had complete control over the size of the "spread."

8. PCCA's scheme was plain and direct: generate mega-spreads to increase pharmacies' potential profits from using PCCA's ingredients. PCCA implemented its scheme by reporting AWPs that bore no rational relationship to the actual selling prices for its ingredients, and which were often marked up by thousands of percent. PCCA used the inflated AWPs and resulting spreads to induce pharmacies to purchase its ingredients.

[2] NDC stands for National Drug Code. NDCs are unique identifiers, comprised of a three-segment number, assigned to drug products in commercial distribution in the United States.

9. Inflating its AWPs enabled PCCA to charge higher prices than its competitors and to overcome pharmacy customers' complaints about those higher prices by emphasizing the greater reimbursement potential of PCCA's ingredients due to their inflated AWPs.

10. Members of PCCA's senior management instructed PCCA sales representatives to market PCCA's ingredients to its pharmacy customers by highlighting the spread between its ingredients' AWPs and the actual selling prices of those ingredients.

11. PCCA further induced the purchase of its ingredients by rewarding its top customers with annual all-inclusive travel packages.

12. In addition, PCCA advised its pharmacy customers on third-party billing (i.e., submitting claims to insurance payers), how to grow their businesses, how to achieve profitability goals, and how to maximize reimbursement for compound prescription claims. PCCA also identified and promoted formulas for compound drugs that were designed to maximize the pharmacies' reimbursement.

13. PCCA's AWP pricing and promotional practices were highly lucrative for the company and resulted in large increases in PCCA's sales and profits between 2012 and May 2015.

14. PCCA's practices led directly to the widespread abuse of TRICARE, as PCCA's compound pharmacy customers submitted tens of thousands of compound prescription drug claims containing PCCA ingredients for excessive reimbursement based upon PCCA's inflated AWPs.

15. PCCA's scheme to induce pharmacies to purchase its ingredients by fraudulently inflating its AWPs and generating excessive AWP "spreads," with the knowledge that those

ingredients would be included in compound prescription claims submitted to TRICARE for excessive reimbursement, violated the FCA, 31 U.S.C. § 3729(a)(1)(A)-(B), the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the common law.

16. The United States now brings this civil action to recover damages for the harm PCCA knowingly caused to TRICARE, which directly resulted from the submission of false and fraudulent prescription claims totaling hundreds of millions of dollars for compound drugs containing PCCA ingredients.

II. PARTIES

17. The United States brings this action on behalf of the Department of Defense ("DOD") and its component the Defense Health Agency ("DHA"), which administers the TRICARE program.

18. Relator, Peter Hueseman, has been a licensed, practicing pharmacist for approximately 30 years. Hueseman formerly worked at, and partially owned, a compound pharmacy that purchased compound pharmaceutical ingredients and services from PCCA.

19. Defendant, Professional Compounding Centers of America, Inc. ("PCCA"), is a Texas corporation with its principal place of business at 9901 South Wilcrest Drive, Houston, Texas. From at least March of 2012 through at least May of 2015, PCCA sold pharmaceutical ingredients and other products to third parties, including pharmacies, for use in drug compounding. In addition to supplying compound pharmacies and pharmacists with active and non-active chemical ingredients, PCCA sold pharmacy software and laboratory equipment and provided customers with suggested formulas for compound drugs, third-party billing support, and other consulting, training, and education.

III. JURISDICTION AND VENUE

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345 because this action is brought by the United States as a Plaintiff pursuant to the FCA.

21. This Court has personal jurisdiction over PCCA pursuant to 31 U.S.C. § 3732(a) and because PCCA transacts business in the Western District of Texas.

22. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c) because many of the acts complained of occurred within the Western District of Texas.

IV. LEGAL BACKGROUND

A. The False Claims Act

23. The FCA establishes liability to the United States for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B).

24. Individuals or entities who violate the FCA are liable to the United States for treble damages as well as civil penalties of not less than $5,500 and not more than $11,000 for each false claim. 31 U.S.C. § 3729(a)(1); 64 Fed. Reg. 47099, 47103-04 (Aug. 30, 1999) (adjusting civil penalties amount pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990).

25. The FCA is intended to reach all types of fraud, without qualification, that might result in financial loss to the government.

26. "False or fraudulent claims" are not limited to claims containing express falsehoods. Claims may also be false where they implicitly certify that they comply with a material statutory, regulatory, or contractual requirement (known as "implied false certification").

27. A claim for reimbursement from a federal health care program that includes items or services resulting from a violation of the Anti-Kickback Statute "constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g).

28. A defendant is liable under the FCA not only when it knowingly presents false claims to the government, but also when it knowingly "causes [such claims] to be presented." 31 U.S.C. § 3729(a)(1)(A).

29. For purposes of the FCA, "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4).

30. The FCA defines "knowingly" to include actual knowledge, reckless disregard, or deliberate ignorance. *Id.* § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

31. For purposes of the FCA, "claim" means:

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

Id. § 3729(b)(2).

32. The standard of proof under the FCA is preponderance of the evidence. *Id.* § 3731(d).

B. The Federal Anti-Kickback Statute

33. The Anti-Kickback Statute ("AKS") arose out of congressional concern that financial inducements may corrupt professional health care decision-making. Congress was concerned that financial inducements would undermine the goals of ensuring fair competition for federal funds and a market driven by quality of care rather than financial incentives, impose higher costs on federal health care programs, and divert federal funds towards goods and services that are medically unnecessary, of poor quality, or even harmful to patients. To protect the federal health care programs from these harms, Congress enacted a prohibition against offering, soliciting, paying, or receiving kickbacks in any form.

34. The AKS makes it illegal for an individual or entity to knowingly and willfully:

> [O]ffer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2).

35. The AKS punishes violations by imposing a fine of no more than $100,000 or imprisonment for not more than ten years, or both. *Id.* § 1320a-7b(b). Those who violate the

AKS are also subject to exclusion from participation in federal health care programs and civil monetary penalties. *Id.* § 1320a-7a(a)(7).

36. A claim for reimbursement from a federal health care program for items or services resulting from a violation of the AKS "constitutes a false or fraudulent claim for purposes of [the FCA]." *Id.* § 1320a-7b(g). Under this provision, claims submitted to federal health care programs that result from AKS violations are *per se* false or fraudulent within the meaning of the FCA.

37. In 2003, the Department of Health & Human Services, Office of the Inspector General, identified potential health care fraud implications of AWP manipulation by pharmaceutical manufacturers in connection with federal health care programs. Among other things, the Office of Inspector General noted:

> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal healthcare programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product . . . . The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

68 Fed. Reg. 23731, 23737 (May 5, 2003).

38. Specific intent is not required to establish a violation of the AKS. 42 U.S.C. § 1320a-7b(h).

V. THE TRICARE PROGRAM AND COMPOUND DRUG REIMBURSEMENT

39. TRICARE provides health care coverage for active duty military personnel, military retirees, and military dependents.[3] TRICARE is administered by DHA, a component of DOD, and is a federal health care program covered by the AKS. 42 U.S.C. § 1320a-7b(f).

40. TRICARE contracts with Express Scripts, Inc. ("ESI") to administer prescription drug coverage for TRICARE beneficiaries, including the processing, adjudication, and payment of compound prescription claims submitted by pharmacies for reimbursement from TRICARE.[4] ESI pays pharmacies for such claims from a government-funded account created for the purpose of paying TRICARE reimbursement claims.

41. To receive reimbursement from TRICARE for compound prescription claims, a pharmacy must enter into a Provider Agreement with ESI or contract with a pharmacy services administrative organization ("PSAO") to contract with ESI on the pharmacy's behalf. ESI's Provider Agreements incorporate ESI's Provider Manuals as part of those agreements.

42. To obtain reimbursement from TRICARE for compound drugs, pharmacies submit electronic data claims to ESI. Generally, each compound prescription claim submitted to ESI for reimbursement from TRICARE contains, among other things, information about the patient, the prescriber, the pharmacy, the ingredients in the compound drug, certain pricing information for the ingredients, and the date the prescription was filled.

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[3] TRICARE was formerly known as the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS").

[4] Throughout this complaint, all references to claims submitted to TRICARE refer to claims submitted to ESI for processing, adjudication, and payment on behalf of TRICARE.

43. Pharmacies are required to submit prescription drug claims, including compound claims, to TRICARE in the current National Council for Prescription Drug Programs ("NCPDP") Telecommunications Standard format. The NCPDP is a non-profit standards development organization. The NCPDP Telecommunications Standard format was developed to provide a common format for the electronic submission of prescription drug claims and other transactions between pharmacy providers, insurance carriers, third-party administrators, and other responsible parties.

44. During the relevant time period, the industry standard for submission and adjudication of compound pharmacy claims was the NCPDP D.0 standard. Under this standard, for each claim, pharmacies were required to submit specific and detailed information about each ingredient contained within a compound formulation. For example, for each ingredient, a pharmacy was generally required to provide information about: (1) the ingredient's National Drug Code ("NDC"); (2) the quantity of the ingredient; and (3) pricing information for the ingredient. Compound prescription claims generally had to include additional pricing information as well, such as the dispensing fee, patient paid amount, gross amount due, and the pharmacy's usual and customary charge for the medication.

45. During the relevant time period, TRICARE generally reimbursed compound prescription claims based on of the lesser of the following amounts: (1) the sum total of the AWPs (minus a contracted discount) for all ingredients in the compound drug, plus a dispensing fee and level of effort fee; (2) the sum total of the costs submitted by the pharmacy for all ingredients in the compound drug, plus a dispensing fee and level of effort fee; or (3) the pharmacy's usual and customary charge for the medication. The reimbursement amount was

also based on the quantity of each ingredient in the compound. Under this methodology, the reimbursement for compound prescription claims submitted to TRICARE by PCCA customers was frequently determined by the reported AWPs.

46. As described in ESI's Provider Manuals during the relevant time period, the usual and customary charge generally refers to the usual and customary retail price of a covered medication in a cash transaction at the dispensing pharmacy (in the quantity dispensed) on the date the medication is dispensed, including any discounts or special promotions offered on such date. ESI's Provider Manuals prohibit pharmacy providers from undermining the usual and customary or compound price, including by manipulating the usual and customary price or separating cash business from third-party payer business.

47. ESI's Provider Manuals explicitly prohibited pharmacies from submitting compound claims with inflated AWPs or for amounts in excess of the pharmacy's acquisition costs, "taking into account a reasonable markup." Such claims were subject to recoupment and offset.

VI. FACTUAL BACKGROUND AND PCCA'S FRAUD SCHEMES

A. PCCA's Membership Model

48. In order to purchase products from PCCA, a pharmacy generally had to become a PCCA "member" and abide by the terms of a "membership agreement."

49. PCCA's membership agreements required a prospective member to pay a nonrefundable membership fee of between $13,000 and $17,000. Membership was renewable annually with payment of a renewal fee.

50. PCCA's membership agreements also required a PCCA member to purchase between ninety and one hundred percent of its compounding products, including chemicals, from PCCA and/or order PCCA products directly through a local wholesaler. Membership could be terminated at PCCA's discretion if this purchase commitment was not met.

51. A PCCA member pharmacy had access to consultant pharmacist support; business consulting services; billing assistance; trainings and educational programming for pharmacists, pharmacy technicians, and marketers; and access to PCCA's Member's-Only Website and Formula Database, which contained more than 8,000 proprietary compound drug formulas.

B. PCCA's Inflated AWPs

52. PCCA did not itself submit claims for reimbursement to TRICARE. Instead, as a pharmaceutical supplier, PCCA sold ingredients to compound pharmacies who used those ingredients to prepare and dispense prescription compound drugs to patients. PCCA's pharmacy customers submitted claims for payment to TRICARE for compound drugs containing PCCA ingredients.

53. Generally, during the relevant time period, PCCA reported an AWP for all PCCA ingredients used in prescription compound drugs billed to TRICARE. PCCA reported those AWPs to publishers of pharmaceutical pricing data, such as Medi-Span. As set forth in more detail below, PCCA's reported AWPs bore no rational relation to PCCA's actual selling prices for the ingredients, were often marked up thousands of percent, and were false and fraudulent.

54. Those publishers reported PCCA's AWPs in pricing compendia available to federal health care programs, private insurance companies, and other purchasers of prescription drugs.

55. PCCA knew and understood that the AWPs it reported for its ingredients would be used by third-party insurance payers including TRICARE (or ESI) in determining reimbursement amounts to pharmacies that submitted claims for compound drugs containing PCCA ingredients.

56. PCCA knew that its customers viewed AWP as a proxy for an ingredient's reimbursement amount, and PCCA often used the term "AWP" and "reimbursement" interchangeably.

57. PCCA determined both the AWPs it reported for its ingredients and the actual selling prices at which it sold its ingredients to customers.

58. PCCA and its customers generally described the difference between the actual selling price for an ingredient and its AWP as the "spread" or "AWP spread."

59. PCCA knew that many of its customers submitted compound prescription claims to third-party insurance payers, including TRICARE, and that those customers placed value and importance on ingredients with large AWP spreads. Generally, a larger AWP spread meant a greater profit for the pharmacy.

60. PCCA generated extremely large spreads by reporting inflated AWPs to drug pricing compendia that bore no rational relationship to the actual selling price paid by PCCA's customers. These lucrative mega-spreads drove customers to purchase—and bill TRICARE for—PCCA's products.

61. Below is a chart showing the differences between the prices at which PCCA typically sold certain ingredients to many customers in 2014 and the AWPs PCCA reported for those ingredients.

Ingredient	NDC	Range of PCCA's Actual Sales Prices Per Unit (2014)	AWP Reported by PCCA (2014)	Range of Spreads Per Unit	Range of AWP as Percentage of Selling Price
FLUTICASONE PROPIONATE	51927-4330-00	$135.00 – $196.82	$3,630.90	$3,434.08 – $3,495.90	1,845% – 2,690%
GABAPENTIN	51927-4213-00	$0.50 – $0.73	$57.06	$56.33 – $56.56	7,816% – 11,412%
RESVERATROL	51927-4367-00	$1.45 – $1.77	$818.68	$816.91 – $817.23	46,253% – 56,461%
LIDOCAINE HCL	51927-1213-00	$0.16 – $0.17	$4.15	$3.98 – $3.99	2,441% – 2,594%
PENTOXIFYLLINE	51927-4389-00	$0.52 – $0.55	$8.72	$8.17 – $8.20	1,585% – 1,677%
PRILOCAINE	51927-1720-00	$0.60 – $0.92	$18.26	$17.34 – $17.66	1,985% – 3,043%
LEVOCETIRAZINE DIHYROCHLORIDE	51927-4654-00	$5.46 – $6.19	$81.90	$75.71 – $76.44	1,323% – 1,500%
FLURBIPROFEN	51927-2701-00	$0.90 – $1.14	$38.39	$37.25 – $37.49	3,368% – 4,266%
KETAMINE	51927-2790-00	$1.25 – $1.46	$35.28	$33.82 – $34.03	2,416% – 2,822%
CYCLOBENZAPRINE HCL	51927-2501-00	$1.04	$48.77	$47.73	4,689%
BASE LIPODERM	51927-4482-00	$0.12 – $0.18	$2.74	$2.56 – $2.62	1,522% – 2,283%
BASE SPIRA-WASH	51927-4678-00	$0.88 – $1.08	$17.37	$16.29 – $16.49	1,608% – 1,974%
BASE PRACASIL-PLUS	51927-4655-00	$0.54 – $0.60	$12.29	$11.69 – $11.75	2,048% – 2,276%

62. These ingredients had AWPs that ranged from 1,323% to 56,461% of PCCA's selling prices for these ingredients to its top customers. While these examples are illustrative, PCCA's scheme extended broadly to many other ingredients as well.

63. These AWPs were also far in excess of PCCA's 2014 catalog prices for these ingredients (even for the most expensive package size by unit). On information and belief, no customer ever paid PCCA the AWPs that PCCA reported.

64. PCCA's mega-spreads constituted remuneration intended to induce customers to purchase its ingredients. PCCA offered that remuneration to its customers knowing that those

customers would seek and obtain reimbursement from third-party payers, including TRICARE, based on PCCA's inflated AWPs. As a result, PCCA's customers received reimbursement amounts that were hundreds, and often times thousands, of dollars more than what they actually paid to acquire the underlying ingredients in the compound prescription.

C. PCCA Chose to Inflate and Market Its AWPs to Customers Despite Its Own Concerns About the Propriety of Such Practices.

65. PCCA recognized the risks of artificially inflating its AWPs to create large spreads for its customers. PCCA knew that inflating AWPs would drive customers to purchase and submit reimbursement claims for ingredients solely because of their reimbursement potential. PCCA also knew that inflating AWPs would likely trigger audits, scrutiny, and investigations.

66. In a January 2012 email to a pharmacy customer, PCCA's President, Jim Smith, expressed concerns that a competing pharmaceutical supplier had raised AWPs in order to increase customers' reimbursement. He stated: "We witnessed members switching over to that junk base [sold by the competitor] solely because of reimbursement . . . ." Ex.1. He noted that this had predictably triggered "an avalanche of shadow-casting investigations," and stated that, although there was "member pressure" on PCCA to raise its AWPs as well, PCCA would not do so. *Id.*

67. In a January 2012 email sent to Smith and other PCCA employees, PCCA's Vice President for Consulting, Research and Development, and Formulations, Gus Bassani, expressed concerns about arbitrarily raising AWPs to an inflated value: "We believe compounders should be reimbursed fairly for the service they provide, but arbitrarily raising AWPs to an inflated

value, just because you can, is not a good strategy and not one that we advocate or support." Ex. 2.

68. In a February 2012 email sent to members of PCCA's senior management, a PCCA regional sales manager, Richard Harwood, attributed the "ridiculous" AWP inflation by PCCA's competitors to "greed and market share capitalization." Ex. 3. He warned that AWP inflation would bring attention to PCCA's customers, subjecting them to "future audits and potentially destroying the compounding market" in the long run. *Id.*

69. In March 2012, PCCA shifted course. On March 7, 2012, Smith instructed PCCA's Chief Operating Officer, Fabian Zaccardo, to increase the AWPs on all of PCCA's products. Smith explained that the "objective" of the AWP increases was to "protect" customers' profit margins. Ex. 4. Recognizing the activities of a competitor, Smith further stated that "[t]his will mean fairly significant increases in our AWP listings for the products [the competitor] distributes. Our objective here is to give our members every reason to choose PCCA when faced with an option of using [the competitor.]" *Id.*

70. Concerned about scrutiny from third-party payers, including insurance companies, Smith instructed Zaccardo to "use [his] best understanding" of how such price increases were distributed to insurance companies "to increase the likelihood news of our increases is adopted within their systems quickly and unremarkably." *Id.*

71. In an email to senior management two days later, on March 9, 2012, Smith explained that the purpose of PCCA's AWP increases was to maintain PCCA's market share.

72. On or about March 9, 2012, PCCA significantly raised the AWPs for many of its ingredients and subsequently reported these increases to Medi-Span and other drug pricing

compendia. PCCA increased the AWP for some ingredients by more than 100%. PCCA's AWPs bore no rational relationship to its selling prices for these ingredients. The below chart is illustrative of some of the AWP increases effective March 9, 2012.

Ingredient	NDC	Prior AWP	New AWP	Percent Increase
Fluticasone Propionate	51927-4330-00	$1,500.00	$3,325.00	121.67%
Gabapentin	51927-4213-00	$34.80	$52.25	50.14%
Resveratrol	51927-4367-00	$620.40	$749.70	20.84%
Lidocaine	51927-1213-00	$2.16	$3.80	75.93%
Pentoxifylline	51927-4389-00	$4.92	$7.98	62.20%
Prilocaine	51927-1720-00	$4.92	$16.72	239.84%
Levocetirizine*	51927-4654-00*	$35.00*	$75.00*	114.29%*
Flurbiprofen	51927-2701-00	$24.60	$35.15	42.89%
Ketamine	51927-2790-00	$22.80	$32.30	41.67%
Cyclobenzaprine HCL	51927-2501-00	$36.00	$44.65	24.03%

* increased on June 20, 2012

D. PCCA's Use of Its Inflated AWPs and AWP Spreads to Induce Sales of Its Products.

73. Immediately after implementing across-the-board AWP increases on March 9, 2012, PCCA sought to capitalize on its inflated AWPs to sell its ingredients. PCCA's Vice President of Sales, Ari Pailakian, planned a two-day Senior Sales Meeting on March 15 and 16, 2012, during which PCCA senior executives, including its President, instructed PCCA sales personnel on topics such as the "AWP marketplace" and "AWPs – How to maximize our sales in this new pharmacy landscape." Ex. 5.

74. PCCA knew that high AWPs and AWP spreads were important to many customers because they could be very lucrative for the pharmacies. PCCA used its high AWPs and AWP spreads to induce its pharmacy customers to purchase PCCA ingredients, which PCCA knew would be billed to insurance and third party payers including TRICARE.

75. PCCA's AWP increases were an important part of its overall pricing and promotional strategy for selling its ingredients. PCCA typically charged more than its competitors for its ingredients, which enabled PCCA to earn greater revenues. But that meant that, unless PCCA's products offered the possibility of higher reimbursement rates from insurers, customers that were price-sensitive would opt for competitors' products.

76. Members of PCCA's senior management frequently instructed PCCA sales personnel to compete not on price, but on AWP reimbursement. For example, in August 2012, in response to a sales representative's request for a price quote for a customer, PCCA's COO, Fabian Zaccardo, explained: "[PCCA's] prices are higher for all these products but you cannot approach them just on price. Our AWPs are significantly more profitable for them if they buy PCCA products. I have provided a breakdown that you can share with them. This needs to be conveyed directly to the owner as this [sic] profit dollars he is losing." Ex. 6. The PCCA sales representative responded that the customer "ordered every item today except the Baclofen, they will order that within the next week. They also added several other items to that order. Thank you for the great information sir." *Id.*

77. In response to a request by a pharmacy customer for PCCA to lower the selling price of certain PCCA ingredients to within 15 percent of a competitor's selling price, PCCA's

COO instructed a sales employee to "emphasize" to the customer that "our AWP spread greatly outweighs any price differences." Ex. 7.

78. In response to another price quote request for a customer, PCCA's COO noted in August 2012: "Our pricing for Flurbiprofen is more expensive but make sure that you explain the difference in reimbursement. Make sure the owner knows this." Ex. 8.

79. In response to another price quote request for a customer in August 2012, PCCA's Director of Member Services instructed a PCCA sales representative: "Is AWP important to [the customer]? If so then you know what to do. Our AWPs far outweighs [sic] any cost difference between us and [a competitor]. [The customer's] re-imbursement would be significantly greater." Ex. 9.

80. To further induce sales of its ingredients, PCCA identified and promoted certain lucrative compound formulas to demonstrate how much money customers could make by purchasing and billing insurance for PCCA ingredients. Many of the compound formulas that PCCA promoted involved pain, wound, and scar creams, containing many ingredients with high AWPs and large AWP spreads.

81. A written update prepared for senior management in July 2012 discussed a meeting between PCCA employees and various compound pharmacy owners who were referred to as "decision makers in California." The update described these "decision makers" as "salivating when we were showing the new . . . Formulas and Reimbursement." Ex. 10.

82. In a conference call with PCCA sales representatives in July 2012, PCCA's Vice President of Sales relayed that he had shared some formulas with PCCA customers, and "[w]hen sharing . . . the acquisition cost versus reimbursement – they were very shocked." Ex. 11.

83. PCCA's COO created a reimbursement calculator known as the "Pain Cream Rx Insurance Calculator," which he shared with PCCA's senior management, including the company's President and Chief Financial Officer, in September 2012. The calculator allowed the entry of "competitor information" and showed "specific Reimbursement dollars per product and formula." Ex. 12. In addition, the calculator had "drop down boxes for the products and competitors" and could "pull in AWPs and profit margins." *Id.* The calculator was set up as an indicator of how much profit a customer could make from billing for PCCA's ingredients. The calculator allowed a PCCA employee to "print a copy of the report on one page [which could] be easily sent to the customer." *Id.*

84. On some occasions, PCCA further increased already-inflated AWPs in response to specific customer requests.

85. On May 24, 2012, a PCCA employee wrote to PCCA's COO and CFO that she received a complaint from a customer who was upset about the AWP for mechlorethamine HCL. PCCA's COO responded that the customer "paid $800.00 for the chemical and [his] net reimbursement for the 25g would be $10,625 . . . The AWP is already double what it should be but I'll go ahead and raise it to $1000/g." Ex. 13.

86. On June 19, 2012, a compound pharmacy in Texas and one of PCCA's top customers emailed PCCA for a price quote on Levocetirizine. The next day, it emailed PCCA's COO asking whether PCCA could "bump up" the AWP for Levocetirizine. Ex. 14. The COO immediately responded: "AWP is at $35/g. I think for the price of the product, it's pretty good. If I raise AWP then I have to raise the prices." *Id.* Nonetheless, less than 30 minutes later, the

COO instructed his assistant to "[p]lease raise the AWP for [Levocetirizine] to $75.00/g," and he informed the pharmacy of this change. Ex. 15.

87. PCCA maintained a database known as "Pivotal" where PCCA sales personnel documented and summarized their sales calls to PCCA's customers. The Pivotal database contains several examples of PCCA sales personnel using AWPs to sell PCCA ingredients, highlighting the prospect of increased reimbursement to induce the purchase of PCCA ingredients, and suggesting various formulas containing ingredients with high AWPs as part of the sales process.

88. On May 13, 2012, a PCCA sales representative reported the following about an in-store customer visit: "We talked about awp's and the major differences that are between pcca and [a competitor]. [She] was really blown away with the difference between the numbers, she realizes that going with pcca they have an opportunity to really make money." Ex. 16.

89. On May 31, 2012, a PCCA sales representative reported the following in an email with a client: "Praca-sil and Spira-Wash are used in [sic] for wound care. I attached the promo flyers above. You can make a killing off this stuff. Praca-sil is used similar to polyox bandage but has healing properties as well and used for scarring or stretch marks. Spira-Wash is similar but can be used with open wounds. These two products have killer AWP's." *Id.*

90. On June 22, 2012, a PCCA sales employee wrote the following in an email to a client: "I am going to share with you some new products that could potentially make you . . . a lot of money. It's Pracasil and Spira-Wash. They both have excellent AWP (great investment return). They are both used in the wound care market. I have also attached the promotional fliers and formula sheets for compounding combinations using APIs [active pharmaceutical

ingredients] with Pracasil and Spira-Wash. Attached are some formulas that are being used in pain management and wound care. Pharmacies are beginning to catch onto the wave of pain management and 3rd party billing. Here are a list of products to consider when marketing to doctors." *Id.*

91. On July 20, 2012, a PCCA employee reported on a meeting with a client: "[Another PCCA official] then went on the [sic] explain the [sic] how the acquisition costs was [sic] really minute in the process when one was taking insurance. He explained the AWP's and demonstrated how our products brought more to the bottom line regardless of costs. [The customer] stated he would give PCCA as much business as he could but it would take a few months to get things sorted out." *Id.*

92. On July 25, 2012, a PCCA sales employee noted in the Pivotal database that he "[w]ent over out [sic] spreads and AWP" with a customer. *Id.*

93. On August 7, 2012, a PCCA sales representative emailed a customer attaching "a few formulas . . . along with a listing of AWP's for most of those products." He noted that the formulas "are being billed ranging from $600-$5200 a script" and that some formulas available from PCCA "bill[ed] out for quite a bit more." *Id.*

94. On August 29, 2012, a PCCA sales representative reported the following exchange with a client: "I also asked if they were billing more 3rd party and they are. We then discussed AWP's and the benefit of buying our chemicals. They do understand that it may cost more to buy our superior product but that they will make it back and then some thru reimbursement." *Id.*

95. On September 6, 2012, a PCCA sales representative had the following exchange in an email with a client: "Here is the NDC list, I am sure when you look at our awp compared to what the [competitor's] are it will be no comparison ours are far better and will make you guys more money." *Id.*

96. On October 16, 2012, a PCCA sales employee reported that they talked to a PCCA customer, and "[s]he said that she constantly look[s] for the best AWP and I told her that we have higher AWP from [competitors]." *Id.*

97. On December 4, 2012, a PCCA sales employee noted that he provided a customer with AWPs for PCCA's and its competitors' ingredients for comparison purposes.

98. On February 20, 2013, a PCCA sales representative had the following exchange with a client: "Spirawash Gel base is typically used in wound care. The base itself can actually be used by itself as it has healing properties within it. There are some formulation examples on our promo page. We do have practitioner specific flyers for this base if you would like to use those in your marketing efforts. Most of the API's used in these formulas have AWP's that are very favorable." *Id.*

99. On April 5, 2013, a PCCA sales representative reported on a meeting with a client: "I met with [the customer] in her new store. I went over complete AWP picture and how to bill 3rd party effectively. After I started talking she would not let me leave." *Id.*

100. On April 22, 2013, a PCCA sales representative sent an email to a pharmacy stating, "[a]lso, I know [another PCCA employee] mentioned looking at our AWP's to help you see the value of our products." *Id.*

101. On May 1, 2013, a PCCA sales representative had the following exchange with a client: "I will say that most of the time I will not be cheaper than [a competitor]. When ordering large quantities I can be much more competitive but price is only part of the equation. PCCA will excel in the AWP arena and you and your bosses will be very pleased with the results." *Id.*

102. On June 4, 2013, a PCCA sales representative reported the following after an in-store visit with a client: "He was unaware that our awp's are higher than most other competitors and was really interested in giving that a try." *Id.*

103. On August 30, 2013, a PCCA sales representative reported the following exchange with a client: "I also reminded her they are not honoring their PCCA contract and without doing so, they are in jeopardy of losing their membership. She will advise the owners. I showed her where she would make more with our AWP;s [sic] as well as reap the benefits of being a Diamond member next year." *Id.*

104. On September 17, 2013, a PCCA sales representative wrote the following to a client: "Also, look into using Fluticasone with wound care and especially with Loxasperse. Formulas are available online. The AWP on that item is very lucrative." *Id.*

105. On October 15, 2013, a PCCA sales representative reported the following regarding a phone call with a client: "He is looking for something else to get into so we talked about scar and wound care. He said our Pracasil is expensive especially since they don't get reimbursed for it. I mentioned how he would for the API's. I gave him some formulas along with #10261 with Fluticasone and we talked about the AWP's. He began to grow interested and sees the potential." *Id.*

106. On December 10, 2013, a PCCA sales representative reported talking with a customer who "had some [competitor] actives for pain creams on her shelves, but I assured her she would make up the money on the back end with our AWP's, so she told me would switch [sic]." *Id.*

107. On February 6, 2014, a PCCA sales representative reported the following about an in-store visit with a client: "He brought up the big difference in price and we had the whole AWP/billing discussion. He recently started doing a pain formula but had no clue how much more he could be making if he billed [insurance]." *Id.*

108. On April 7, 2014, a PCCA sales representative reported the following about a sales call with a client: "I asked if he is taking advantage of our formulas and AWP's with fluticasone and collagenase. He didn't know about these so I gave him the formula numbers and he jotted them down." *Id.*

109. On May 8, 2014, a PCCA sales representative reported the following about a phone call with a client: "I called [the customer] to check in and talk about Fluticasone. He orders Pracasil from us but order[s] Fluticasone from [a competitor]. I let him know that [another competitor] has this in customs and not sure about [the competitor], but we have plenty in stock. Although he doesn't buy it from us, I talked about our higher AWP and how it also goes towards his Rewards and GIB [Growth Incentive Bonus]." *Id.*

110. On December 8, 2014, a PCCA sales representative had the following email exchange with a client: "The best that I can do on the Sumatriptan will be around $13 per gm if you order 5 containers. Plus you will get the benefits from our Growth Incentive Program which

will add an additional 5% on top of that. I don't know [a competitor's] AWP but I know ours is very favorable $170.47 per gm." *Id.*

111. On January 24, 2015, a PCCA sales representative emailed a customer about several products, noting that the "AWP's have a great spread." *Id.*

E. PCCA Assisted Customers in Maximizing Profitability from Its AWPs.

112. PCCA's efforts to assist its members in maximizing profits from third-party billing extended beyond simply inflating its AWPs. For example, PCCA also provided members with training, consulting services, and its own billing software that pharmacies could use to submit claims to third-party payers.

113. PCCA held educational seminars on topics including third-party billing. These included discussions on how to utilize PCCA's AWPs to "work the [reimbursement] spread" and "get the widest spread possible."[5]

114. PCCA also offered its members a business consulting service called Compounding Pharmacy Management Services ("CPMS"). CPMS included consulting on issues such as third-party billing and "custom prescription pricing strategies." Ex. 17.

115. Bill Letendre was Vice President of PCCA's CPMS program and was a business coach to PCCA's customers. Letendre and other CPMS coaches worked with PCCA's customers to help them achieve certain target profit margins for their compound pharmacy business. CPMS offered "prescription pricing and profitability analysis." *Id.* This entailed analyzing a customer's prescription data to generate a "Prescription Profitability and Performance Report." *Id.* These

[5] These quotations are from audio recordings produced by PCCA pursuant to a civil investigative demand.

reports measured the customer's sales, profits, and inventory replacement costs and identified areas where changes could be made to increase the pharmacy's profitability.

116. In CPMS marketing materials, one customer stated: "Bill Letendre's guidance with marketing, pricing and managing has been invaluable to us. He and his team continue to help by monitoring our sales profitability and our cash flow . . . . We find this service to be extremely valuable." *Id.* Another PCCA member stated that "[s]ince joining CPMS, we have seen consistent increase in our gross margin. . . . This has directly resulted in additional profit for our pharmacy." *Id.*

117. PCCA also assisted pharmacy customers in manipulating their reported usual and customary prices. PCCA offered billing software, called PK Software. Among other things, customers could use PK Software to submit claims to third-party payers, including TRICARE. The software included features that enabled customers to manipulate the usual and customary price submitted with the claim to ensure that reimbursement of compound claims was based on AWP as opposed to an alternative lower price. This included a setting that allowed a pharmacy to automatically report its usual and customary price as the same as the AWP-based price. The manual for the software warned that "[i]f you use this check box, and get audited, you will need to justify to the insurance the reason you raised for [sic] U&C." Ex. 18.

F. PCCA Knew That Its Inflated AWPs Resulted in Inflated Billing, Overutilization of Its Ingredients, and Abusive Billing Practices.

118. PCCA knew that its customers submitted claims to TRICARE for compound drugs containing PCCA ingredients. PCCA actively monitored TRICARE's compound drug reimbursement policies. For example, the agenda for a January 2014 Senior Management Meeting included a "Tricare Update." Additionally, PCCA and its sales representatives

communicated with PCCA member pharmacies about TRICARE's compound drug coverage. For example, in June 2014, PCCA prepared an "Update on TRICARE Coverage" for distribution to PCCA members.

119. Some PCCA personnel expressed concerns about the large AWP spreads that were driving business between PCCA and its competitors. In an email from July 2012, PCCA's Director of Outside Sales, Danyce Ashton, explained that "AWPs (average wholesale price) for the ingredients are how members are being paid" and that many customers were "shifting their business with reimbursement levels – to heck with value." Ex. 19. Ashton expressed concerns that PCCA had "lots of members charging the system $2500 - $3000 per script that normally would sell for around $75.00" and that she was "very uncomfortable with the way people are billing." *Id.* Ashton concluded by observing that "[w]e [PCCA] have had the biggest revenue year in our history but this house is built on sand. And I'm anxious in advance over the air coming out of the balloon." *Id.*

120. In an email chain from August 2014, one PCCA executive, Charlie Armstrong, wrote to members of PCCA's senior management about the exorbitant amounts pharmacies were billing to third-party payers:

> I don't believe the jokers who have been raping the insurance companies realize that they have killed the goose that laid the golden egg!! They were too green to remember what Russell Sharp said in the early 1980s: "You can shear a sheep many times but can skin him only once."

Ex. 20.

121. In response to Armstrong's email, PCCA's Vice President of Sales, Fabian Zaccardo, wrote to PCCA's COO, Ari Pailakian, "I don't think Charlie realizes that all those

increases in our dividends are mostly due to insurance." Ex. 21. PCCA's COO responded, "Yeah and made him a millionaire. He is losing it." *Id.*

122. Among the ingredients for which PCCA established and reported highly inflated AWPs were fluticasone propionate (NDC No. 51927-4330-00) and resveratrol (NDC No. 51927-4367-00).

123. These two PCCA ingredients were particularly lucrative for both PCCA and its customers. Between 2012 and 2015, these two PCCA ingredients were included in almost 28,000 compound prescription claims paid by TRICARE, and they accounted for over $216 million in TRICARE compound drug costs. The United States attaches as Exhibit 22 examples of 325 inflated compound prescription claims submitted to TRICARE for these and other PCCA ingredients. Each of these compound prescription claims was reimbursed at thousands of dollars per prescription. Exhibit 22 is incorporated by reference. For each claim, Exhibit 22 identifies the date the compound prescription was dispensed, the dispensing pharmacy, the pharmacy state, the payment status, the amount paid, the ingredients contained within the compound prescription claim as submitted, and the corresponding NDC for each ingredient.

1. Fluticasone Propionate

124. Fluticasone propionate belongs to a class of drugs known as fluorinated corticosteroids. Fluorinated groups added to topical corticosteroids increase their strength and skin penetration. A prescription topical cream containing 0.05% fluticasone propionate is commercially available and approved by the FDA "for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses." *See*

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=657aee47-558f-4634-a566-fc81dab2fabc (last visited October 29, 2021).

125. PCCA generated extremely large AWP spreads for fluticasone propionate, which made it immensely profitable for compound pharmacies to use.

126. Between 2012 and 2015, PCCA more than doubled its reported AWP for fluticasone propionate, increasing it from $1,500 per gram to $3,757.98 per gram. In 2014, PCCA's AWP for fluticasone propionate was $3,630.90 per gram, whereas it typically sold this ingredient to its top customers for between $135.00 and $196.82 per gram. Put another way, PCCA generated a "spread" of more than $3,400 for each gram of fluticasone propionate billed by a compound pharmacy in 2014.

127. PCCA heavily promoted sales of fluticasone propionate and formulations containing fluticasone propionate, and it used the ingredient's substantial AWP spread to induce pharmacies to purchase this ingredient from PCCA over its competitors.

128. PCCA did so despite knowledge that its inflated and extraordinarily lucrative AWP was causing widespread abuse of this chemical by compound pharmacies. A February 2015 email between PCCA sales personnel discussed that there was "controversy on how [fluticasone propionate] is used" and that a PCCA internal pharmacy consultant had talked at a "Global Sales Training" about "how Fluticasone is being abused because of the high AWP and reimbursements." Ex. 23. That email further discussed that "[t]here are a lot of other chemicals that can be used in place of Fluticasone that are just as beneficial, but reimbursements are higher and members are making a lot of money." *Id.*

129. To promote the use of its fluticasone propionate, PCCA promoted numerous compound drug formulations containing this ingredient. Among these were formulas for "skin lightening" and "scar[s]." *Id.* Some of the fluticasone topical cream formulas promoted by PCCA contained 1% fluticasone propionate, or 20 times the FDA approved dosage. *See supra* ¶ 124 (0.05% fluticasone propionate cream). Because AWP-based reimbursement accounted for the quantity of the ingredient, these fluticasone formulations containing 1% fluticasone were extremely lucrative for PCCA's customer pharmacies.

130. PCCA knew that formulations containing 1% fluticasone propionate were potentially harmful. A PCCA internal pharmacy consultant, Brian Prescott, wrote in an August 20, 2014 email to a colleague at a compound pharmacy specifically about "a wound cream with 1% fluticasone." Ex. 24. Prescott asked the colleague, "Do you have any idea why the formula would be written that way? It's a disturbing trend. . . . It is widely documented in the literature that steroids (especially high dose and chronic use) delays [sic] the immune response, delays collagen deposition, and delays wound contracture . . . bad, bad, bad." *Id.* The colleague responded that "[a]s crappy as it is, pharmacies are using fluticasone in formulas because of the super high AWP reimbursement. It's done for financial reasons, therapeutics be darned." *Id.* PCCA nonetheless continued to promote formulations containing 1% fluticasone propionate.

131. According to an internal PCCA document, by February 2015, skin and scar creams containing 1% fluticasone propionate comprised two of PCCA's "[t]op three [fluticasone] formulas trending." Ex. 23. In discussing ways to market fluticasone to customers, that same document discussed marketing to "AWP lovers" who were "doing 3rd party billing." *Id.*

132. As a result of PCCA's AWP inflation and marketing efforts, fluticasone propionate became PCCA's top selling ingredient by 2015.

133. PCCA's inflated AWP spreads directly resulted in a dramatic increase in its customers' use of PCCA's fluticasone propionate. In 2012, PCCA's customers submitted approximately 400 compound prescription claims containing PCCA's fluticasone propionate to TRICARE. In the first four months of 2015 alone (from January to May), PCCA's pharmacy customers submitted over 16,000 compound prescription claims containing PCCA's fluticasone propionate to TRICARE.

134. Between 2012 and 2015, TRICARE paid over $180 million for PCCA's fluticasone propionate. PCCA's pharmacy customers frequently billed and received several thousands of dollars in reimbursement from TRICARE for each compound prescription claim containing PCCA's fluticasone propionate based on the ingredient's inflated AWP.

2. Resveratrol

135. PCCA promoted the chemical resveratrol (NDC No. 51927-4367-00), which is a "Metabolic Supplement," or a nutritional supplement taken to boost metabolism. In particular, PCCA promoted a "Metabolic Supplement" formula containing resveratrol and several other ingredients commonly found in off-the-shelf nutritional supplements.

136. Prices for over-the-counter resveratrol supplements vary, but products with quantities totaling at least 10 grams of resveratrol can be found online for less than $50.

137. PCCA typically sold resveratrol to customers for under $2 per gram.

138. On March 9, 2012, PCCA raised its AWP for resveratrol from an already inflated $620.40 per gram to $749.50 per gram—350 times PCCA's typical selling price for the

ingredient. By January 2015, PCCA had further increased the AWP for resveratrol to $847.33 per gram, or more than 400 times PCCA's typical selling price. This created a spread between PCCA's typical selling price and the AWP it reported of more than $840 per gram.

139. PCCA's increases in AWP—and the lucrative "spreads" that resulted—created an incentive for its customers to purchase and utilize resveratrol in compound formulations billed to third-party payers like TRICARE. This caused a dramatic increase in PCCA customers' use of resveratrol in compound prescription claims. In 2012, only 2 compound prescription claims utilizing PCCA's resveratrol were billed to TRICARE. By 2015, this number had skyrocketed. In the first four months of 2015 (from January to May), PCCA's pharmacy customers submitted over 4,000 compound prescription claims containing PCCA's resveratrol to TRICARE.

140. PCCA's pharmacy customers frequently billed and received several thousands of dollars in reimbursement from TRICARE for each compound prescription claim containing PCCA's resveratrol based on the ingredient's inflated AWP. One PCCA pharmacy customer billed and received from TRICARE over $46,000 per claim for several compound claims containing resveratrol and other PCCA ingredients with inflated AWPs.

G. PCCA Rewarded Its Most Loyal Customers with All-Inclusive Trips.

141. In addition to its AWP spreads, PCCA offered additional inducements to incentivize members to purchase PCCA products. PCCA members could qualify for participation in PCCA's in-house rewards program based on the volume of PCCA products they purchased. PCCA's rewards program had four tiers: Silver, Gold, Platinum, and Diamond.

142. If a pharmacy's annual purchases from PCCA were $300,000 or more, the pharmacy qualified for Diamond level membership.

143. PCCA rewarded its Diamond level members with annual all-inclusive trips, known as "WOW" trips, to destinations such as Cancun, Mexico. PCCA marketed WOW trips in part through flyers sent to PCCA members. These flyers described WOW trips as being "complimentary" and "our sun-soaked, fun-filled way to say 'thanks' for being such a loyal PCCA member." Ex. 25.

144. On July 22, 2014, John O'Brien, PCCA's then-Director of Member Relations, wrote to PCCA Diamond Members, thanking them for their business and discussing that Diamond level benefits included two all-expense paid registrations to the annual Diamond WOW trip in 2015. As explained by O'Brien, PCCA paid for flights, hotel rooms, food and drink, and various excursions and resort activities for a PCCA member and their guest.

145. The 2014 WOW trip to Cancun, Mexico included zip-lining, golfing, visiting Mayan ruins, and swimming with dolphins.

146. PCCA used its WOW trips as a marketing tool to induce additional purchases from its customers. For example, in December 2013, a PCCA sales representative wrote to a customer stating that they were on track to hit Diamond level: "I know that you had mentioned that you would like to hit Diamond this year. . . . You are currently at $294k and need to spend at least $6k between now and the end of the year to hit Diamond. As you know, that will get you some FREE education and an invite to our WOW event in Cancun next May." Ex. 26.

147. On August 7, 2014, a PCCA sales representative wrote to a customer: "You guys are currently sitting at the Platinum level with PCCA. However you [are] roughly around $37K away from hitting the Diamond level. If you guys are able to get to that point by the end of September you will get Diamond status for the rest of 2014 as well as all of 2015." Ex. 27. He

explained that, among other benefits, this "comes with our Diamond Exclusive Package which this year we took all of our Diamond members to Mexico for 5 days as a paid vacation for 2." *Id.*

148. In December 2014, a PCCA sales representative wrote to a customer congratulating them on reaching Diamond level, saying "I hope you have your suitcase ready for the Diamond WOW Trip!!!!" Ex. 16.

149. PCCA also used its WOW trips as a "negotiating tool" to get customers to agree to certain purchasing "commitments" in advance. In January 2014, PCCA wrote to a customer whose business it was trying to retain: "Not only will PCCA be able to cover 2 people we will be able to cover yourself, Leo, Mark, and your wives, for the Diamond Exclusive Event to Cancun, Mexico at no charge. We will cover your airfare, resort rooms, excursions, food, drinks, and resort activities." Ex. 28. PCCA officials, including PCCA's Vice President of Sales, discussed internally that this was being offered "in order for us to have a continued relationship in purchasing," and that PCCA needed to obtain commitments from the customer in return. *Id.*

H. PCCA Caused Its Customers to Submit False Claims to TRICARE.

150. By setting inflated AWPs, marketing the spread, coaching its customers on how to submit claims to third party insurance, and as further detailed in this complaint, PCCA played a direct and substantial role in causing the submission of false or fraudulent claims for excessive reimbursement to TRICARE.

151. It was a direct, foreseeable, and intended consequence of PCCA's actions that PCCA's pharmacy customers would submit claims for reimbursement to TRICARE.

I. PCCA Knew That Its Inflated AWPs Were Material to TRICARE's Reimbursement.

152. PCCA knew that its grossly inflated AWPs were material to reimbursement amounts from third-party payers like TRICARE.

153. PCCA sought to prevent third-party payers and auditors from learning the magnitude of its AWP spreads—which constituted remuneration—by concealing its selling prices from them.

154. PCCA was concerned that disclosure of its selling prices, when compared to the AWPs it reported, could lead third-party payers, including TRICARE, to limit or discontinue paying for expensive compound prescription claims. For example, in a March 2013 email, a PCCA senior account representative advised PCCA's senior management that a pharmacy benefit manager had conducted a 12 month audit of a PCCA customer and "disallowed almost all compounds using PCCA chemicals because the cost was overcharged. Medco is questioning the prices because the [pharmacy benefit manager's] auditor said they had a PCCA pricing book. i.e. $300 submit and $37 was the amount Medco said was the cost according to the PCCA pricing book." Ex. 29.

155. When a PCCA customer requested that PCCA change the format of its invoices to include the AWP along with the cost of the ingredients, PCCA declined to do so. In an email dated May 10, 2012, to PCCA's Director of Member Services, PCCA's COO explained that "[t]his would not be a very good idea. The insurance companies request copies of the invoice and they would be able to see both the AWP and cost in one location." Ex. 30.

156. In seminars on third-party billing and auditing that PCCA held for its members in late 2013 or 2014, PCCA representatives urged its members never to divulge PCCA's selling

prices (also referred to as the pharmacy's "acquisition costs") when requested by insurance auditors, saying: "Please, do not ever give them your costs." "You need to call us." "Do not give them your costs, ever. It's going to create huge problems for you." PCCA warned its customers "don't let [auditors] see your acquisition costs. That is a disaster waiting to happen."[6]

157. If an auditor requested invoice information from a PCCA customer, PCCA advised customers to call PCCA and, in response, PCCA would generate a report for the auditor that would exclude the actual selling prices of PCCA's ingredients from the report.

158. PCCA enjoyed explosive growth in the sales of its ingredients between 2012 and 2015 because of its AWP pricing practices. In 2011, PCCA's annual revenue from sales of its ingredients was approximately $71 million. In 2012, PCCA's sales grew to over $100 million. In 2013, PCCA's sales grew to $161 million. And in 2014, PCCA's sales grew to almost $250 million. PCCA's growth came at the direct expense of the TRICARE program.

159. PCCA recognized that TRICARE's continued coverage of its compound drug ingredients and bases was critical to PCCA's continued profits. In an email dated March 20, 2014, a lobbyist used by PCCA wrote to PCCA's President about "the latest on the TRICARE compounded pharmacy situation," stating that "there will be a further delay in their (TRICARE/DOD) decision." Ex. 31. The lobbyist wrote that "another delay equals another victory for PCCA and ALL of your member pharmacies." *Id.*

160. In November 2014, the Department of Defense's Pharmacy and Therapeutics ("P&T") Committee unanimously recommended a prior authorization process for compound

[6] These quotations are from audio recordings produced by PCCA pursuant to a civil investigative demand.

prescription claims. The P&T Committee found that the recommended prior authorization process would maintain accessibility for compound drugs when appropriate while allowing for needed scrutiny.

161. Following input from the Beneficiary Advisory Panel, the Director of DHA approved a plan for an enhanced electronic screening and prior authorization process for compound prescription claims. The enhanced screening process was effective on May 1, 2015. As a direct result, the number of compound prescription claims submitted to TRICARE declined sharply.

162. PCCA's sales plummeted. In an email dated June 1, 2015, PCCA's President acknowledged that "Tricare changes in reimbursement took a huge toll on our members' purchases. Wowzer!" Ex. 32. In the same email chain, which contained the subject title "May Sales," PCCA's monthly sales declined from over $24.5 million in May 2014 to $14.9 million in May 2015.

163. According to an internal PCCA document, PCCA's annual revenue declined from over $244 million in 2014 to under $90 million in 2015. According to that document, the sharpest declines came from PCCA's "Diamond" level customers.

J. TRICARE Reimbursement Criteria and PCCA's Reported AWPs Are Both Material to the Payment of Compound Prescription Claims.

164. PCCA's AWPs were material to the amount TRICARE paid for compound prescription claims containing PCCA's ingredients. Had PCCA's AWPs not been grossly inflated, TRICARE would not have reimbursed for PCCA's ingredients at the inflated amounts.

165. Any provider seeking reimbursement from TRICARE must comply with TRICARE's anti-fraud and abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE's regulations

provide that fraud or abuse by a pharmacy or other provider may result in denial of the provider's claims or the exclusion or suspension of the provider from participation in the TRICARE program. *Id.* §§ 199.9(b), (f). Compliance with the fraud and abuse regulations are material to TRICARE's payment decision.

166. TRICARE's regulations state that fraudulent situations include arrangements between a supplier and provider that result in claims that include unnecessary costs or charges to TRICARE. *Id.* § 199.9(c)(13). Fraudulent situations also include arrangements between suppliers and providers, including kickback arrangements, designed to overcharge TRICARE. *Id.* § 199.9(c)(12).

167. TRICARE's regulations state that abusive situations include billing TRICARE at rates in excess of those routinely charged to the general public or other third-party payers for similar services or billing substantially in excess of customary or reasonable charges. *Id.* § 199.9(b)(2), (7).

168. TRICARE's regulations specify that "[a]ll fraud, abuse, and conflict of interest requirements [in section 199.9] are applicable to the TRICARE pharmacy benefits program." 32 C.F.R. § 199.21(p). TRICARE's contract with ESI also incorporates the provisions of 32 C.F.R. § 199.

169. To qualify for reimbursement from TRICARE, a drug must be "medically or psychologically necessary [for] the diagnosis and treatment of illness or injury." 32 C.F.R. § 199.4(a)(1)(i); *see also* 32 C.F.R. §199.4(g)(15). For a drug to be medically or psychologically necessary, it must, among other things, constitute "appropriate medical care" as defined in TRICARE's regulations. 32 C.F.R. § 199.2. This requires that the care be "furnished

economically." *Id.* Compound prescription claims that do not meet the coverage requirements in 32 C.F.R. §§ 199.4(a)(1)(i) and 199.4(g)(15) are not reimbursable by TRICARE. The coverage requirements in 32 C.F.R. §§ 199.4(a)(1)(i) and 199.4(g)(15) are express conditions of payment by the TRICARE program. Additionally, these coverage requirements go to the essence of the bargain under the TRICARE program and ensure that TRICARE reimburses only for reasonable and necessary prescription drug costs.

170. On May 1, 2015, an enhanced screening procedure and prior authorization process for compound prescription claims was implemented by TRICARE.

171. TRICARE took this action directly in response to the exorbitant reimbursements that were being paid for compound prescription claims containing PCCA and other compound pharmaceutical suppliers' ingredients.

172. As a direct result of DHA's enhanced screening and prior authorization procedures, the number of compound prescription claims submitted to and paid by TRICARE declined sharply.

173. PCCA's conduct, as alleged above, was a systematic effort to profit at the expense of the TRICARE program, resulting in hundreds of millions of dollars in damages.

174. The United States has used the FCA to recover from other compound ingredient suppliers for monies TRICARE paid for compound ingredients with grossly inflated AWPs. *See, e.g.*, https://www.justice.gov/opa/pr/compound-ingredient-supplier-fagron-holding-usa-llc-pay-2205-million-resolve-allegations (last visited October 28, 2021).

K. Compliance with the AKS is Material to TRICARE's Payment Decision.

175. The AKS is a criminal statute designed to prevent fraud and abuse of federal health care programs like TRICARE. As such, it is central to TRICARE's payment decision.

176. The materiality of the AKS is demonstrated by Congress's express determination that any claim for reimbursement from a federal health care program, including TRICARE, that includes items or services resulting from a violation of the AKS "constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g).

177. The ESI Provider Manuals in effect from August 2013 through May 31, 2015, expressly required pharmacies to comply with all state and federal anti-kickback statutes. Pursuant to those Provider Manuals, failure to demonstrate compliance with such laws could result in immediate termination by ESI.

178. The United States regularly enforces the AKS, including through the pursuit of FCA liability based on underlying AKS violations. Additionally, DHA has exercised its authority to exclude or suspend providers found to have committed fraud or abuse, including the payment of kickbacks.

L. The United States Suffered Damages.

179. As a result of PCCA's actions as alleged in this complaint, TRICARE paid hundreds of millions of dollars in excess reimbursement for tens of thousands of false and fraudulent compound prescription claims containing PCCA ingredients submitted by PCCA's customers. Examples are included in Exhibit 22.

FIRST CAUSE OF ACTION
(False Claims Act: Causing False or Fraudulent Claims)
(31 U.S.C. § 3729(a)(1)(A))

180. The United States re-alleges and incorporates by reference the allegations of Paragraphs 1 through 179.

181. By virtue of the acts described above, PCCA knowingly caused to be presented for payment or approval false or fraudulent TRICARE claims, in violation of the False Claims Act, 31 U.S.C.§ 3729(a)(1)(A); that is, PCCA knowingly caused to be presented false or fraudulent claims for inflated reimbursement amounts for compound drugs paid for by TRICARE.

182. By virtue of the acts described above, PCCA knowingly caused to be presented for payment or approval false or fraudulent TRICARE claims, in violation of the False Claims Act, 31 U.S.C.§ 3729(a)(1)(A); that is, PCCA knowingly caused to be presented false or fraudulent TRICARE claims that were the result of Anti-Kickback Statute violations in the form of lucrative "AWP spreads" and/or all-expense paid trips that were intended to induce pharmacies to purchase ingredients from PCCA.

183. Payment of the false and fraudulent claims was a reasonable and foreseeable result of PCCA's conduct.

184. By reason of the foregoing, the United States suffered actual damages because of PCCA's wrongful conduct in an amount to be determined at trial and therefore is entitled under the False Claims Act to treble damages plus a civil penalty for each false or fraudulent claim.

SECOND CAUSE OF ACTION
(False Claims Act: False Statements Material to False Claims)
(31 U.S.C. § 3729(a)(1)(B))

185. The United States re-alleges and incorporates by reference the allegations of Paragraphs 1 through 179.

186. By virtue of the acts described above, PCCA knowingly made, used, or caused to be made or used false records or statements that were material to false or fraudulent TRICARE claims; that is, PCCA established fraudulent and grossly inflated AWPs, which it reported to commercial pricing compendia.

187. The fraudulent AWPs were material to and were actually relied on in determining TRICARE reimbursement for claims for compound drugs containing PCCA's ingredients.

188. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of PCCA's statements and actions.

189. By reason of the foregoing, the United States suffered actual damages because of PCCA's wrongful conduct in an amount to be determined at trial and therefore is entitled under the False Claims Act to treble damages plus a civil penalty for each false record or statement material to a false or fraudulent claim.

THIRD CAUSE OF ACTION
(Payment by Mistake)

190. The United States re-alleges and incorporates by reference the allegations of Paragraphs 1 through 179.

191. This is a claim by the United States under federal common law for the recovery of monies that TRICARE paid by mistake in the form of excessive reimbursement based on

PCCA's false and inflated AWPs, and for compound prescription claims that were tainted by PCCA's illegal remuneration to its pharmacy customers.

192. As a consequence of PCCA's conduct and the acts set forth above, TRICARE mistakenly or erroneously paid amounts to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States. PCCA benefitted from the mistaken payments.

FOURTH CAUSE OF ACTION
(Unjust Enrichment)

193. The United States re-alleges and incorporates by reference the allegations of Paragraphs 1 through 179.

194. This is a claim by the United States under federal common law for recovery of monies by which PCCA has been unjustly enriched due to its actions described in this complaint.

195. By virtue of the conduct and the acts described above, PCCA was unjustly enriched at the expense of the United States in an amount to be determined, which, under the circumstances, in equity and good conscience, and as dictated by the needs of justice and fairness, should be returned to the United States or would be unconscionable for PCCA to retain.

196. By virtue of the conduct and the acts described above, PCCA obtained a benefit at the expense of the United States by fraud, duress, or the taking of unfair advantage.

FIFTH CAUSE OF ACTION
(Common Law Fraud)

197. The United States re-alleges and incorporates by reference the allegations of Paragraphs 1 through 179.

198. This is a claim by the United States under federal common law.

199. PCCA knowingly made material and false representations concerning the pricing of its pharmaceutical ingredients, with the intention to deceive the United States and with the intention for the United States to act upon such misrepresentations to its detriment. The United States acted in justifiable reliance upon PCCA's false representations in making payments for compound prescription claims submitted by PCCA's pharmacy customers to TRICARE.

200. PCCA's false representations caused the United States to make payments it would not have made had PCCA made truthful representations.

201. By reason of these payments, the United States has been damaged in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully prays for judgment in its favor as follows:

202. As to the First and Second Causes of Action (False Claims Act), for: (i) statutory damages in an amount to be established at trial, trebled as required by law, and such penalties as are required by law; (ii) the costs of this action, plus interest, as provided by law, and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

203. As to the Third Cause of Action (Payment Under Mistake of Fact), for: (i) an amount equal to the money paid by the United States through the TRICARE program as a consequence of Defendant's conduct, plus interest; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

204. As to the Fourth Cause of Action (Unjust Enrichment), for: (i) an amount equal to the money paid by the United States through the TRICARE program as a consequence of

Defendant's conduct, or the amount by which Defendant was unjustly enriched, plus interest, (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

205. As to the Fifth Cause of Action (Common Law Fraud), for: (i) compensatory and punitive damages in an amount to be determined at trial, (ii) the costs of this action, plus interest, as provided by law, and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

206. All other and further relief as the Court may deem just and proper.

DEMAND FOR A JURY TRIAL

The United States hereby demands a jury trial on all claims alleged herein.

DATED: October 29, 2021

Respectfully submitted,

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